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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,121	01/24/2005	Stanley George Bonney	PG4885USw	8414

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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,121	BONNEY ET AL.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/24/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specifically, the patent documents listed in paragraphs 0097, 0134, 0224, 0228, 0230, and 0250 are missing from the information disclosure statement.

2. The information disclosure statement filed January 24, 2005 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Specifically, EP 521432 is not listed on the information disclosure statement.

3. The information disclosure statement filed January 24, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, WO 01/39823, WO 02/04055, WO 03/061744 and EP 521434 is listed on the information statement but no copy has been provided to the Office.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 424, 501, 510, 516, 520, 1010a, and 1110.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 501a, 501b, 510a, 510b, 516a, 516b, 520a, and 520b.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of

any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-10, 23, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (6,234,167).

As to Claim 1-4, 8, 23, and 37, Cox discloses a medicament dispenser device (121) for use in the delivery of a multi-component combination medicament product, the device comprising: a first medicament container (37) containing a plural co-formulation compatible medicament components; a first release means for the contents first medicament container for delivery thereof (35); at least one further medicament container (137), each containing at least one co-formulation incompatible medicament component; and at least one further release means for releasing the contents of each at least one further medicament container for delivery thereof (135), wherein the at least one co-formulation incompatible medicament component is kept separate from the plural co-formulation compatible components until the point of release thereof for delivery in combination. Regarding the co-formulation limitation, Cox discloses the

medicament containers may include two or more components mixed together before the material is volatilized. (Column 9, Lines 52-66 and Figure 3).

As to Claim 5 and 10, Cox discloses an aerosol generator (121) is an inhaler device. (Column 3, Lines 45-60).

As to Claim 6, Cox discloses the first medicament container and the second medicament container may be similar or different. Specifically, Cox discloses the first and second medicament container may be held at the same or different pressures to facilitate the delivery of the medicament to the patient. Thus inherently, the first medicament container may be similar to the second medicament container when the co-formulations are held a the same pressure or the first medicament container may be different from the second medicament container when the co-formulations are held at different pressures. (Column 8, Line 47 thru Column 9, Line 12).

As to Claim 9, Cox discloses a mixing chamber (29) including a first inlet (the location between the release means 35 and element 29) for receiving the released contents of the first medicament container (37), a second inlet (the location between the release means 135 and element 29) for receiving the released contents of the second medicament container (137), and an outlet (the location between element 29 and mouthpiece 53) for the delivery of combination medicament product therefrom.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 11-22, and 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (6,234,167) in view Marfat et al. (6,559,168).

As to Claims 11-22, and 24-36, Cox discloses a medicament device, yet does not expressly disclose the recited medicaments. However at the time the invention was made the use of the recited medicaments was well known. Specifically, Marfat discloses all the recited medicaments are known and used in the treatment of respiratory diseases such as asthma, chronic bronchitis, and chronic obstructive pulmonary disease. (Column 209-256). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include the medicaments, as taught by Marfat, to be used in the treatment of respiratory diseases.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 9-23 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 37, 61-66, 71, and 72 of copending Application No. 10/502,519. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 9 is merely broader than copending application claims 1, 37, 61, and 62. It is clear that all of the elements of claim 9 are found in copending claims 1, 37, 61, and 62. The difference lies in the fact that the copending claim includes many more elements and is thus much more specific. Thus, the invention of the copending claims 1, 37, 61, and 62 is in effect a "species" of the "generic" invention of the instant claim 9. It has been held that the

generic invention is "anticipated" by the "species". See In Re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 9 is anticipated by claim 1 of the copending application, it is not patentably distinct from copending claims 1, 37, 61, and 62.

With respect to all the claims the copending application recites plural medicament carriers, a dispenser for dispensing distinct does from each medicament carrier, and a receiving station for receiving the dosage from the medicament carrier, while the instant claim recites a first and second medicament container a first and second release means, a mixing chamber, and a co-formulation of the medicament being released.

The limitations of instant claim 10-23 are found in copending claims 63-66, 71 and 72.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1, 9-11, 13, 14, 16, 23-37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, and 18-22 of copending Application No. 10/522,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1 and 9 are merely broader than copending application claim 1. It is clear that all of the elements of claims 1 and 9 are found in copending claim 1. The difference lies in the fact that the copending claim includes many more elements and is thus much more specific. Thus, the invention of the copending claim 1 is in effect a "species" of the

"generic" invention of the instant claims 1 and 9. It has been held that the generic invention is "anticipated" by the "species". See In Re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1 and 9 is anticipated by claim 1 of the copending application, it is not patentably distinct from copending claim 1.

With respect to all the claims the copending application recites a first and second medicament container, a first and second release means, a mixing chamber, while the instant claim recites a first and second medicament container a first and second release means, a mixing chamber, and a co-formulation of the medicament being released.

The limitations of instant claims 10 and 11 are found in copending claims 17-19.

The limitations of instant claim 13 are found in copending claim 22.

The limitations of instant claim 14 are found in copending claim 20.

The limitations of instant claim 16 are found in copending claim 21.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Makiej Jr. (5,002,048) and Weinstein (6,571,790).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

JUSTINE R. YU
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3/30/07